

## PATENT COOPERATION TREATY BEST AVAILABLE COPY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION CONCERNING  
SUBMISSION OR TRANSMITTAL  
OF PRIORITY DOCUMENT

(PCT Administrative Instructions, Section 411)

To:

POLIZZI, Catherine, M.  
Morrison & Foerster L.L.P.  
755 Page Mill Road  
Palo Alto, CA 94304-1018  
ETATS-UNIS D'AMERIQUE

Date of mailing (day/month/year) 03 August 1998 (03.08.98)	<b>IMPORTANT NOTIFICATION</b>
Applicant's or agent's file reference 304142000340	
International application No. PCT/US96/20757	
International publication date (day/month/year) 26 June 1997 (26.06.97)	
International filing date (day/month/year) 19 December 1996 (19.12.96)	Priority date (day/month/year) 20 December 1995 (20.12.95)
Applicant UNIVERSITY OF KENTUCKY RESEARCH FOUNDATION et al	

1. The applicant is hereby notified of the date of receipt (except where the letters "NR" appear in the right-hand column) by the International Bureau of the priority document(s) relating to the earlier application(s) indicated below. Unless otherwise indicated by an asterisk appearing next to a date of receipt, or by the letters "NR", in the right-hand column, the priority document concerned was submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b).
2. This updates and replaces any previously issued notification concerning submission or transmittal of priority documents.
3. An asterisk(\*) appearing next to a date of receipt, in the right-hand column, denotes a priority document submitted or transmitted to the International Bureau but not in compliance with Rule 17.1(a) or (b). In such a case, the attention of the applicant is directed to Rule 17.1(c) which provides that no designated Office may disregard the priority claim concerned before giving the applicant an opportunity, upon entry into the national phase, to furnish the priority document within a time limit which is reasonable under the circumstances.
4. The letters "NR" appearing in the right-hand column denote a priority document which was not received by the International Bureau or which the applicant did not request the receiving Office to prepare and transmit to the International Bureau, as provided by Rule 17.1(a) or (b), respectively. In such a case, the attention of the applicant is directed to Rule 17.1(c) which provides that no designated Office may disregard the priority claim concerned before giving the applicant an opportunity, upon entry into the national phase, to furnish the priority document within a time limit which is reasonable under the circumstances.

<u>Priority date</u>	<u>Priority application No.</u>	<u>Country or regional Office or PCT receiving Office</u>	<u>Date of receipt of priority document</u>
20 Dece 1995 (20.12.95)	08/575,762	US	26 Febr 1997 (26.02.97)
29 Janu 1996 (29.01.96)	08/591,965	US	26 Febr 1997 (26.02.97)
13 Dece 1996 (13.12.96)	not furnished	US	NR

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AUG 19 1998

MATRIX CUSTOMER  
SERVICE CENTER

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. (41-22) 740.14.35	Authorized officer Beatriz Morariu Telephone No. (41-22) 338.83.38
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From the INTERNATIONAL BUREAU

PCT

COMMUNICATION IN CASES FOR WHICH  
NO OTHER FORM IS APPLICABLE

To:

POLIZZI, Catherine, M.  
Morrison & Foerster L.L.P.  
755 Page Mill Road  
Palo Alto, CA 94304-1018  
ETATS-UNIS D'AMERIQUE

Date of mailing (day/month/year)

25 July 1997 (25.07.1997)

Applicant's or agent's file reference

304142000340

REPLY DUE

see paragraph 1 below

International application No.

PCT/US96/20757

International filing date (day/month/year)

19 December 1996 (19.12.1996)

Applicant

UNIVERSITY OF KENTUCKY

1. ☐ REPLY DUE within \_\_\_\_\_ months/days from the above date of mailing☐ NO REPLY DUE, however, see below☒ IMPORTANT COMMUNICATION☐ INFORMATION ONLY

2. COMMUNICATION:

Please be informed, in respect of the above-identified international application, that, consequent to the applicant's timely filed request for rectification of an obvious error according to PCT Rule 91, the receiving Office has informed the International Bureau (WO) that the rectification is to be authorized as requested by the applicant.

The priority claim(s) in Box VI of the request form (form PCT/RO/101) should read:

COUNTRY

FILING DATE

APPLICATION NO.

US

29 January 1996 (29.01.96)

08/591,965

instead of

COUNTRY

FILING DATE

APPLICATION NO.

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26 January 1996 (26.01.96)

08/591,965

Copies: The receiving Office (RO/US)

The designated Offices concerned

The International Bureau of WIPO  
34, chemin des Colombettes  
1211 Geneva 20, Switzerland

Facsimile No. (41-22) 740.14.35

Authorized officer

Beate Giffo-Schmitt

Telephone No. (41-22) 338.83.38

From the INTERNATIONAL BUREAU

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755 Page Mill Road  
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Facsimile No. (41-22) 740.14.35	Telephone No. (41-22) 338.83.38

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# PATENT COOPERATION TREATY

## PCT

REC'D 09 MAR 1998

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### INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference N.73404 DMG/SMW	<b>FOR FURTHER ACTION</b>		See Notification of Transmittal of International Preliminary Examination Report (PCT/IPEA/416)
International application No. PCT/US96/20757	International filing date (day/month/year) 19/12/1996	Priority date (day/month/year) 20/12/1995	
International Patent Classification (IPC) or national classification and IPC C12N15/13			
Applicant UNIVERSITY OF KENTUCKY et al.			

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.



2. This REPORT consists of a total of 5 sheets, including this cover sheet.

- ☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☒ Certain observations on the international application

Date of submission of the demand 17/07/1997	Date of completion of this report 04.03.98
Name and mailing address of the IPEA/   European Patent Office D-80298 Munich Tel. (+49-89) 2399-0. Tx: 523656 epmu d Fax: (+49-89) 2399-4465	Authorized officer  Vollbach. S  Telephone No. (+49-89) 2399-8715 

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/US96/20757

## I. Basis of the report

1. This report has been drawn on the basis of (*substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.*):

### Description, pages:

1-95 as originally filed

### Claims, No.:

1-58 as originally filed

### Drawings, sheets:

1/28-28/28 as originally filed

2. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

4. Additional observations, if necessary:

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/US96/20757

## V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

### 1. Statement

Novelty (N)	Yes:	Claims 1-58
	No:	Claims
Inventive step (IS)	Yes:	Claims
	No:	Claims 1-58
Industrial applicability (IA)	Yes:	Claims 1-58
	No:	Claims

### 2. Citations and explanations

**see separate sheet**

## VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

**see separate sheet**

SECTION V

The quoted documents are:

- (1) Cancer Research, vol. 55, (1995), pages 1525-1530
- (2) WO 89/07268

D1 describes the preparation of the monoclonal anti-idiotypic antibody designated 11D10 which corresponds to the antibody described in the present application.

One might argue that the (deposited) antibody constitutes a unique entity which is not identically reproducible.

However, even if one accepted that the deposited antibody 11D10 is not identically reproducible, it remains the fact that the isolation of said anti-idiotypic antibody by using another specific antibody named BrE1 is described in D1. Said other antibody, BrE1, however is available in the art (see D2).

Thus, when following the disclosure of D1 by using the antibody BrE1, the skilled person would at least be in the position to isolate anti-idiotypic antibodies which are equivalent to the deposited antibody 11D10.

Thus, even if novelty were to be accepted, an inventive activity had to be denied in view of the disclosure of D1 in combination with D2.

In this context it has to be mentioned that most of the claims are not even directed to the specific antibody or the corresponding hybridoma but have a much broader scope ("having identifying characteristics..").

The other claims have no inventive merit per se but their possible inventive activity depends on the inventive activity of the (deposited) antibody.

For the assessment of the present claims 46 to 50 and 53 on the question whether they are industrially applicable, no unified criteria exist in the PCT. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT - SEPARATE SHEET**

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International application No. PCT/US96/20757

claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

**SECTION VIII-----**

1. Claims 6 and 20 relate to polypeptides (or the corresponding DNA) having immunological activity of monoclonal anti-idiotypic 11D10, wherein the polypeptide comprises at least 5 contiguous amino acids of the variable region".  
On the one hand, the "immunological activity" is not clearly defined (see page 11, line 24ff).  
On the other hand the panel of the uncountable number of different antibodies which are, in addition to the "activity", merely defined by a stretch of "5 contiguous amino acids" must be considered as being not sufficiently disclosed.  
Finally, the various polypeptides and nucleotide sequences which are covered by said claims, are no longer connected by a common inventive link.  
In fact, the only link which connects the various claimed entities is an activity which is not even novel.